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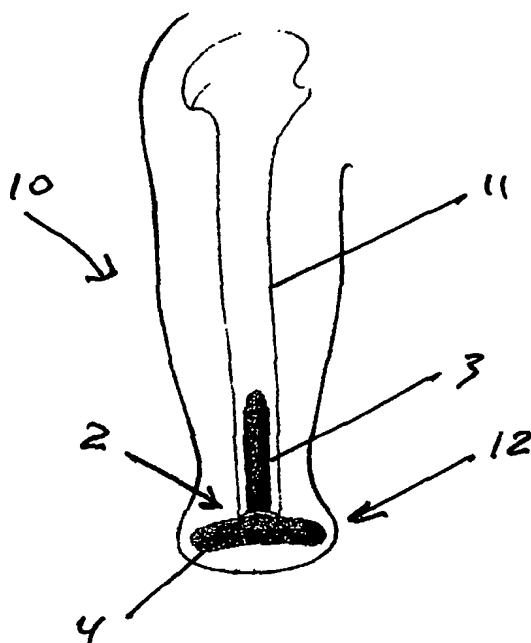
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(54) Title: PROSTHESIS SET

(57) Abstract: Prosthesis set (1) for persons with amputated
limbs/stumps (10) where the prosthesis set consists of an anchoring
part (2) arranged internally in a remaining marrow bone (11) and
an external prosthesis (7). The anchoring part (2) has a bolt-like
design with a stem (3) and an expanded head (4) in one end,
wherein the stem (3) can be inserted and anchored in the remaining
marrow bone (11). The expanded head (4) forms a subcutaneous
termination of the marrow bone (11) and a local expansion (12)
at the end (10) of the amputated limb. The external prosthesis (7)
has an internal design (8) adapted to the local expansion.

"Prosthesis set"

5 The present invention relates to a prosthesis set for persons with amputated limbs/stumps where the prosthesis set consists of an anchoring part arranged internally in a remaining marrow bone and an external prosthesis.

Traditionally, exogenous prostheses are for example for upper arm amputees fastened to a person by vacuum or straps etc. that are fastened around the
10 persons upper torso, i.e. neck and shoulders. Such prostheses are thus very bulky and cumbersome in use, uncomfortable and offer limited movement for the person using them. Poor anchoring of the prosthesis sleeve also reduces movement and feeling with the prosthesis. The person using the prosthesis often experiences problems with wear and tear, back problems, neck problems, problems
15 with sweat, strangulation etc. Another problem with such prostheses is that pressure forces from the prosthesis against the end of the amputated bone can cause extensive pain, and in the worst case the bone stump can penetrate through the skin at the contact point with the prosthesis.

DE 3 125 268 A1 solves the problem of absorbing the pressure forces described above by having a bolt inserted into the end of the bone to absorb the
20 pressure forces and functions like a "shock absorbing cushion". This publication does not, however, contribute to improving the anchoring of an exogenous prosthesis.

There is today another solution that offers a better prosthesis function than
25 the solution described above. In this connection reference is made to DE 4 338 746 A1, which comprises a prosthesis set for persons with amputated limbs/stumps. The prosthesis set consists of an anchoring part arranged internally in a remaining marrow bone and an external prosthesis. The anchoring part or fastening arrangement to the bone extends through the skin and the solution is
30 not therefore a closed (subcutaneous) system. The anchoring part or the titanium bolt penetrates the skin and this creates a great risk of infection for the patient. The risk of infection means the patient must daily disinfect the wound (which will never heal) in the area where the titanium bolt penetrates the skin. The risk of infection further implies that only a small number of patients qualify for such an

implant. Another weakness with a non-closed system is that the patient experiences discomfort due to the transfer of heat/cold. The titanium bolt, which is exposed to the outer environment, transfers heat/cold into the tube skeleton. Some patients are also very sensitive to jolts, since the jolts spread through the bolt and into the tube skeleton. There are no soft parts between the stump and the exogenous prosthesis that can absorb these forces. This solution requires several surgical operations with 6-9 months intervals, which puts great strain on the patient.

One objective of the present invention is to create a prosthesis set for persons with amputated limbs/stumps where the prosthesis sleeve is better anchored to the amputated limb or stump, thus improving the function of the prosthesis.

Another objective is that the prosthesis shall have a simple fastening locally to the amputated stump, and that the prosthesis can be anchored distally to the stump. Such an anchoring of the prosthesis will increase the degree of freedom, i.e. mobility is improved.

A third objective is that the user of the prosthesis shall be able to put weight on the end of the prosthesis as well as transfer torsion forces from the stump to the prosthesis.

A fourth objective is that the prosthesis set shall be able to be applied to all amputated limbs, for example humerus, femur, tibia, fibula, ulna, radius, etc.

A fifth objective of the invention is that it shall be possible to extend the amputated stump to obtain the most ideal stump length for fastening an external prosthesis.

The objectives of the invention are achieved by a prosthesis set for persons with amputated limbs/stumps where the prosthesis set consists of an anchoring part arranged internally in a remaining marrow bone and an external prosthesis characterised by that the anchoring part has a bolt-like shape with a stem and an expanded head at one end, wherein the stem can be inserted and anchored in the remaining marrow bone and that the expanded head forms, respectively, a subcutaneous termination of the marrow bone and a local expansion at the amputated limb's end and that the external prosthesis has an internal shape adapted to the local expansion.

Preferred embodiments of the prosthesis set are further described in the claims 2-9.

5 Preferred embodiment examples of the present invention will now be explained with reference to the Figures, where

Fig. 1 shows a person with an amputated upper arm,

Fig. 2 shows the person from Fig. 1 equipped with a traditional prosthesis with straps,

10 Fig. 3 shows the amputated upper arm from Fig. 1, and illustrates the first step in a method for implanting an anchoring part for a prosthesis set according to the present invention,

Fig. 4 shows the anchoring part itself,

15 Fig. 5 shows the anchoring part inserted into the upper arm bone of the person in Fig. 1,

Fig. 6 shows a termination of the person's upper arm after the anchoring part has been inserted,

Fig. 7 shows schematically the anchoring part from Fig. 4 and 5 inserted into the upper arm bone,

20 Fig. 8 shows a second embodiment of the anchoring part inserted into a person's marrow bone,

Fig. 9 shows the external prosthesis of the prosthesis set according to the present invention,

25 Fig. 10 shows the prosthesis set arranged on the person's upper arm with an anchoring part inserted. The person is here seen from the front,

Fig. 11 shows the external prosthesis in Fig. 10 now seen from behind,

Fig. 12 shows the prosthesis set in Fig. 11 with the under arm attached,

Fig. 13 shows a third embodiment of an anchoring part according to the invention, now arranged internally in a thighbone,

30 Fig. 14 shows an external prosthesis for a thighbone,

Fig. 15 shows the external prosthesis arranged on the thighbone in Fig.

13,

Fig. 16 shows a fourth embodiment of the anchoring part according to the present invention, and

Fig. 17 shows a fifth embodiment of the connection part inserted into a person's upper arm.

With reference to the Figures above, it must be noted that the same reference numbers are used to designate the corresponding parts throughout the different embodiments of the invention.

Fig. 1 shows a person with an amputated upper arm 10, and Fig. 2 shows the person with a traditional exogenous prosthesis. As Fig. 2 shows, the prosthesis covers the whole upper arm, parts of the shoulder and is further fastened by straps around the neck and shoulders. The prosthesis is large and bulky and has a fastening arrangement that reduces the person's mobility and feeling with the prosthesis. In addition, it is apparent that the user could have problems with wear, sweat, etc.

Fig. 3 shows a first step in a method for implanting an anchoring part 2 belonging to the prosthesis set 1 according to the present invention. A surgical operation 13 is carried out at the end of the amputated upper arm 10 and the amputated end of the marrow bone (the upper arm bone) 11 is uncovered. The anchoring part 2 with stem 3 and an expanded head 4 according to Fig. 4 is inserted into the bone of the upper arm or the marrow bone 11. Before the insertion of the anchoring part 2 the inside of the marrow bone 11 will be drilled out and adjusted to the anchoring part 2 which again will be cemented internally in the marrow bone 11. The stem 3 of the anchoring part will be arranged with one or more longitudinal grooves 6, preferably for applying cement filling. Fig. 6 shows the amputated upper arm 10 with inserted anchoring part 2. As this figure shows, the expanded head 4 of the anchoring part 2 will produce a local expansion 12 at the amputated limb's end 10. This expansion 12 will enable a very good anchoring for an external prosthesis 7 according to the present invention. Fig. 7 shows schematically the anchoring part 2 inserted and cemented inside the marrow bone 11 and illustrates clearly that the expanded head 4 forms a subcutaneous termination of the marrow bone 11 and a local expansion 12 at the amputated limb's end. Head 4 of the anchoring part is here plate shaped and slightly curved.

Fig. 8 shows a second embodiment of the anchoring part 2, now with a local expansion 5 towards the expanded head 4. This second embodiment of the

anchoring part 2 is used in cases where it is necessary to extend the marrow bone 11 to achieve a better fixture of the external prosthesis 7. This will be, for example, in cases where the upper arm 10 is amputated higher up towards the armpit. Fig. 9 shows the external prosthesis 7 as a part of the prosthesis set 1.

5 The external prosthesis 7 is adapted to the amputated upper arm 10 and the local expansion 12 in particular, which is a result of the implanted anchoring part 2. Fig. 10 shows the complete prosthesis set from the front and Fig. 11 shows the complete prosthesis set from behind. As can be seen from Figs. 10 and 11, the external prosthesis 7 is significantly smaller and thus lighter and more user-
10 friendly than the traditional prosthesis shown in Fig. 2. The local fastening of the external prosthesis 7 also contributes to increased freedom of movement and greater comfort for the user. Fig. 12 shows the prosthesis set 1 with attached operationable artificial underarm 9.

Fig. 13 shows a third embodiment of the anchoring part 2 arranged in an
15 amputated thighbone. As the figure shows, the head 4 in particular has a completely different shape and is constructed to absorb greater pressure forces due to the great pressure shock that such a leg prosthesis involves. Fig. 14 shows an external prosthesis 7 for use in connection with the amputated thighbone incorporating the implant according to the present invention. Fig. 15 shows the complete
20 prosthesis set 1 for a person with a leg amputated at the thigh. As Fig. 15 shows, the local expansion 12 and the adapted internal design 8 in the external prosthesis 7 provide a good anchoring. A good "shock-absorbing cushion" is further achieved by means of the anchoring part's expanded head 4.

Fig. 16 shows a fourth embodiment of the anchoring part 2. The head of
25 the anchoring part now has a T-shape and is slightly curved.

Fig. 17 shows a fifth embodiment of the anchoring part 2. The anchoring part's stem 3 now has an expansion 5 nearest the head 4. This expansion 5 serves in this case as an extension of the marrow bone 11 as described in connection with Fig. 8, and would in this case be suitable for a person whose arm
30 has been amputated well above the elbow. The extension of the upper arm bone 11 will give better grip for the external prosthesis 7 and thus increase the prosthesis function for the person.

It should be mentioned that the surgical operation will be carried out by an orthopaedist or surgeon. The implant or the anchoring part 2 is fastened to the

marrow bone (tube bone) 11 by cementing, and this is a technology that is known in applications like hip joint prostheses, knee joint prostheses etc. The implanting of the anchoring part (condyle) is performed surgically, and will thus be healed in 3-4 weeks. This implies that the patient can have full use of the prosthesis set 1 already 4-6 weeks after the operation. The anchoring condyle will be produced in titanium, a material the body does not reject. Surgical steel is another material that can be used. The implant will be in a closed environment, subcutaneous, which to a great extent reduces the danger of infections and transfer of coldness.

Ultimately, it should be mentioned that the invention is not limited to the shown embodiments, in that it can be used for other amputated body parts and modifications can be adapted without leaving the idea of the invention.

Patent claims

1. A prosthesis set (1) for persons with amputated limbs/stumps (10) where the prosthesis set consists of an anchoring part (2) arranged internally in a remaining marrow
5 bone (11) and an external prosthesis (7), wherein the anchoring part (2) has a bolt-like shape with a stem (3) and a head (4) in one end, wherein the stem (3) can be inserted and anchored in the remaining marrow bone (11) and the head (4) forms a subcutaneous termination of the marrow bone (11), characterized by that the anchoring
10 part's head (4) has a width that exceeds the width of the stump (10) so that there is a local expansion/bulge (12) at the amputated limb's end (10) and that the external prosthesis (7) has an internal shaping (8) adapted to the local expansion (12) whereby a local anchorage, suspension and support of the prosthesis sleeve is established.
2. A prosthesis set according to claim 1,
15 characterized by that the stem (3) is arranged with an expansion towards the head (4).
3. A prosthesis set according to claims 1 or 2,
characterized by that the stem (3) is arranged with at least one longitudinal
20 groove (6).
4. A prosthesis set according to each of the previous claims,
characterized by that the head (4) is plate shaped.
- 25 5. A prosthesis set according to claim 4,
characterized by that the plate shaped head (4) is slightly curved.

6. A prosthesis set according to each of the claims 1-3,
characterized by that the head (4) is T-shaped.

7. A prosthesis set according claim 6,
5 characterized by that the T-shaped head (4) is slightly curved.

8. A prosthesis set according to each of the previous claims,
characterized by that the prosthesis set (1) is made of titanium.

9. A prosthesis set according to each of the claims 1-7,
10 characterized by that the prosthesis set (1) is made of surgical steel.

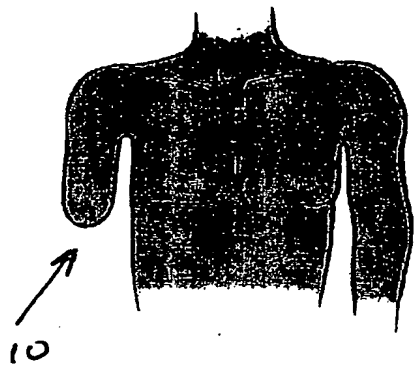


Fig. 1

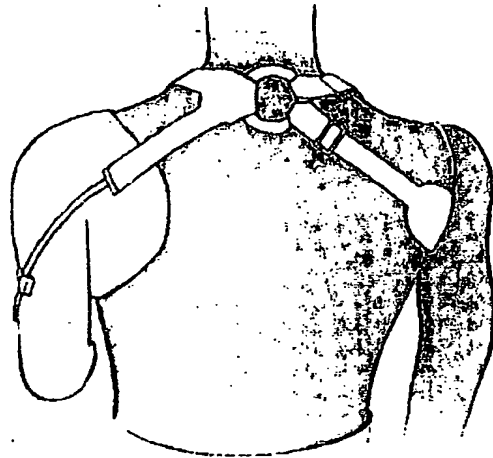


Fig. 2

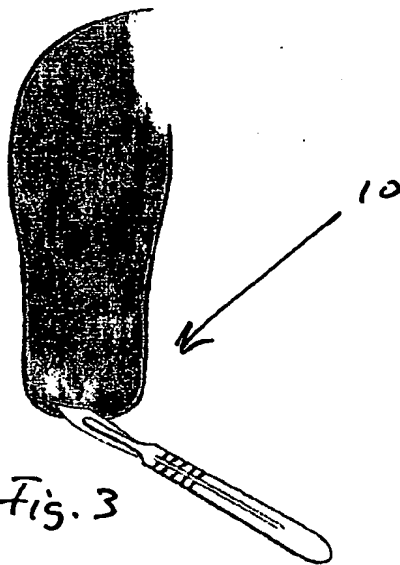


Fig. 3

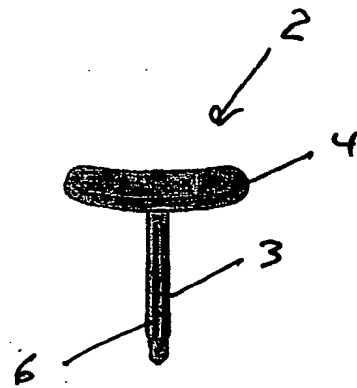


Fig. 4

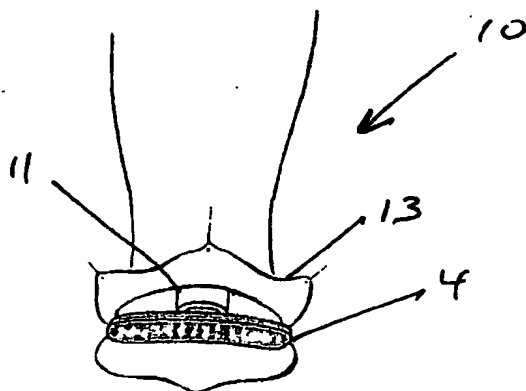


Fig. 5

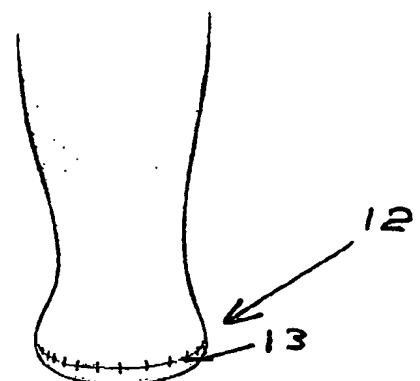
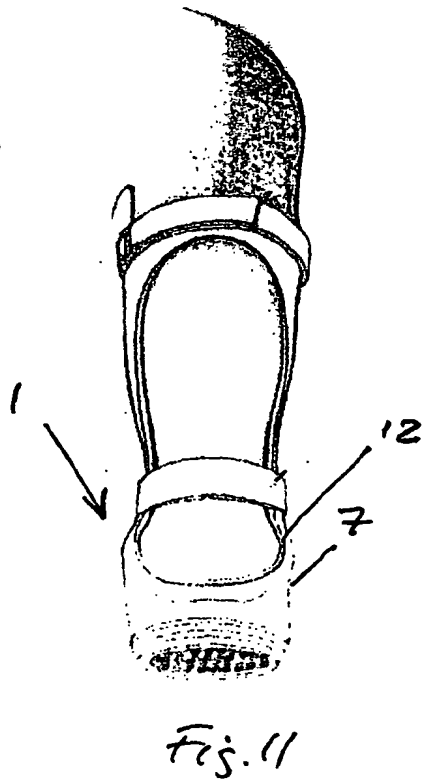
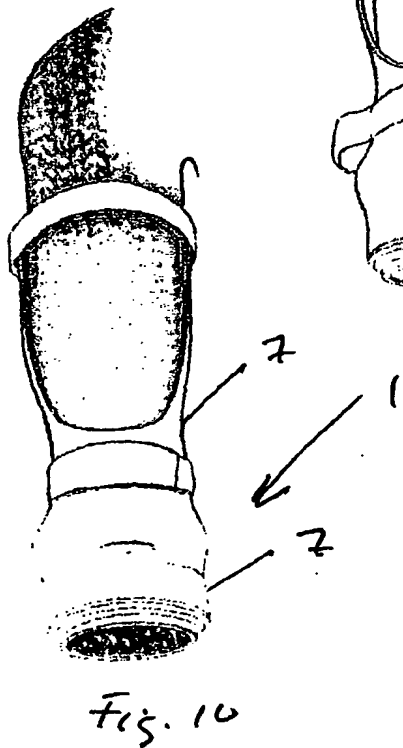
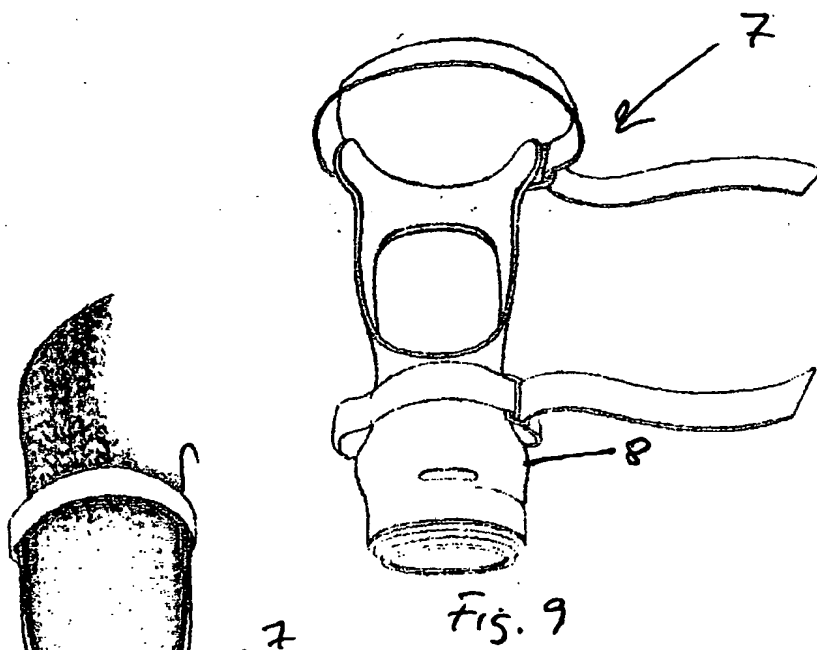
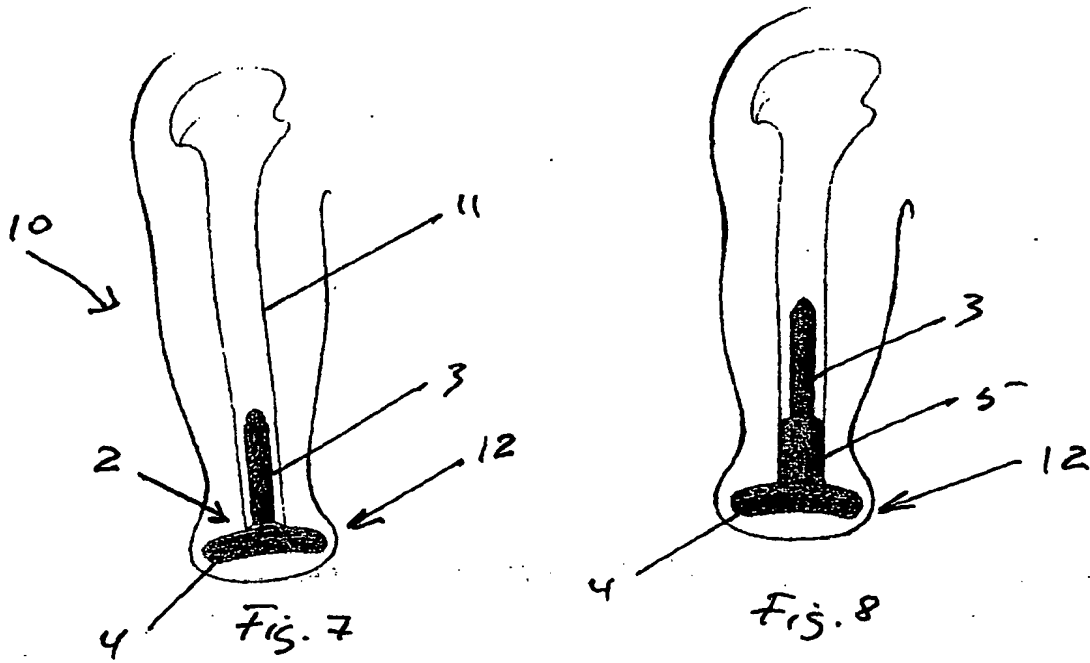
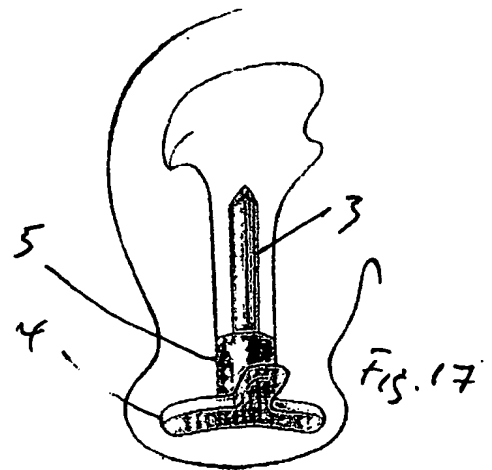
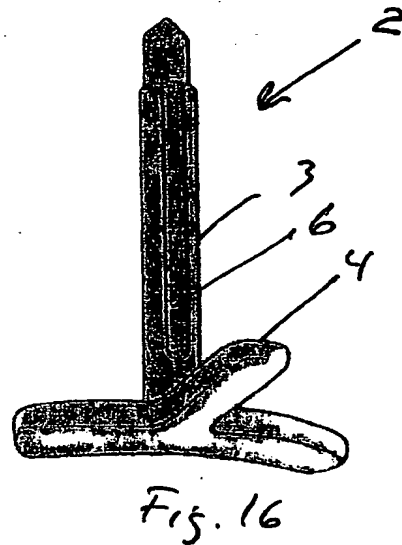
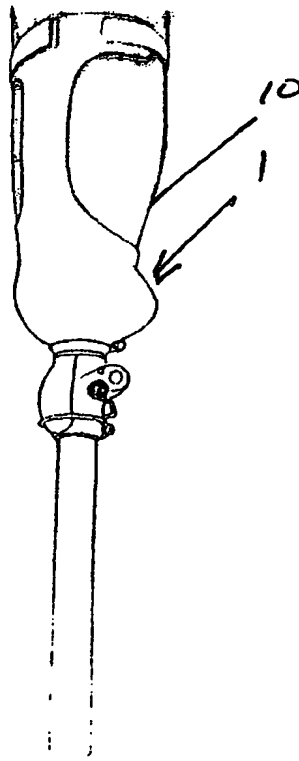
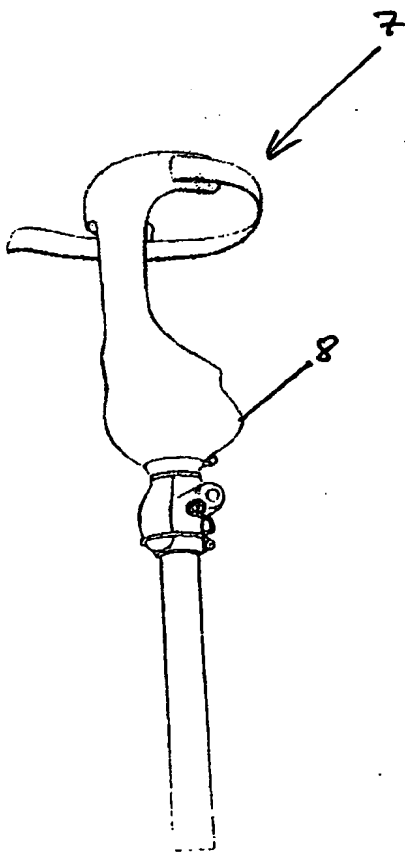
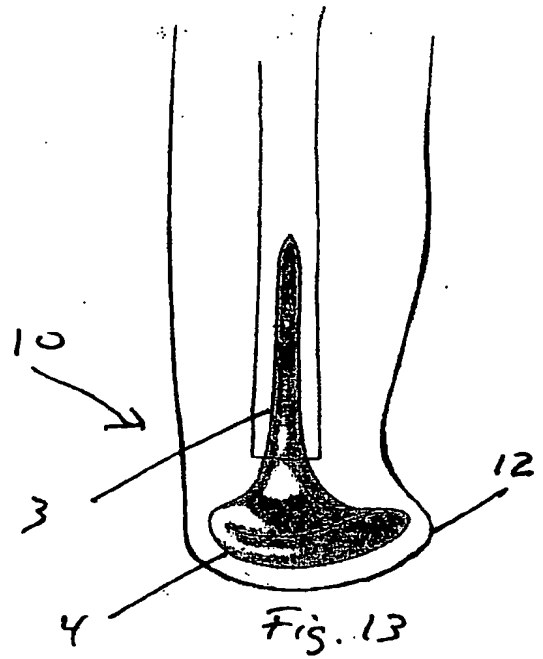
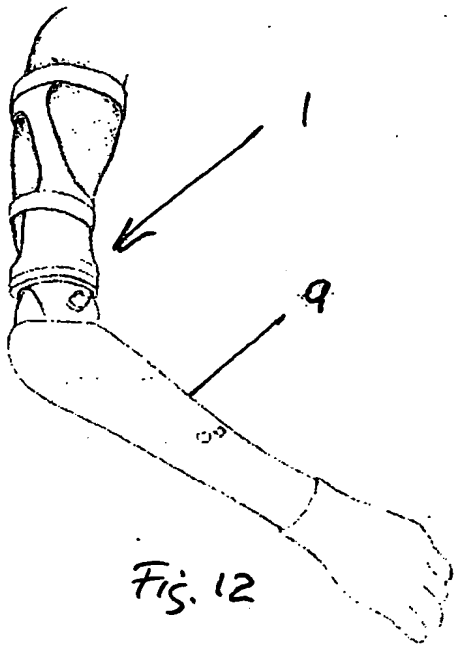


Fig. 6





INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/28, A61F 2/78

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0105335 A1 (ESKA IMPLANTS GMBH & CO.), 25 January 2001 (25.01.01) --	1-9
A	DE 3125268 A1 (C. NICOLAI GMBH & CO), 13 January 1983 (13.01.83), figure 5 --	1-9
A	DE 9400720 U1 (SCHREIBER, HANS), 29 June 1995 (29.06.95), figure 2 --	1-9
A	US 4158895 A (ROBERT A. RESWICK ET AL), 26 June 1979 (26.06.79) -- -----	1-9

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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INTERNATIONAL SEARCH REPORT
Information on patent family members

29/03/03

International application No.

PCT/NO 03/00017

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
WO	0105335	A1	25/01/01	AT 229775 T DE 19932388 C DE 50000961 D EP 1119319 A,B JP 2003504153 T	15/01/03 14/12/00 00/00/00 01/08/01 04/02/03
DE	3125268	A1	13/01/83	NONE	
DE	9400720	U1	29/06/95	NONE	
US	4158895	A	26/06/79	NONE	